

Message Text

UNCLASSIFIED

PAGE 01 TOKYO 15265 01 OF 02 240249Z
ACTION OES-09

INFO OCT-01 EA-12 ISO-00 HEW-06 CIAE-00 DODE-00 INR-10
NSAE-00 PA-02 ICA-20 SP-02 L-03 EB-08 COME-00
MED-05 /078 W
-----092008 240330Z /73
R 240240Z AUG 78
FM AMEMBASSY TOKYO
TO SECSTATE WASHDC 0627

UNCLAS SECTION 01 OF 02 TOKYO 15265

FOR OES/ENP/EN, W. WALSH

DEPT PASS TO DHEW/FDA

E.O. 11652: N/A
TAGS: TBIO, JA
SUBJECT: TOKYO DISTRICT COURT RULING ON SMON CASE

REF: (A) 77 TOKYO 12626, (B) TOKYO 3470

1. ON AUG. 3, TOKYO DISTRICT COURT RULED IN FAVOR OF 133 PLAINTIFFS IN THE TOKYO SMON (SUBACUTE MYLEO-OPTICO NEUROPATHY) CASE. THEY ARE AMONG THE 2,197 PLAINTIFFS IN TOKYO AWAITING COURT DECISION OR SETTLEMENT. THE COURT HELD THAT QUINOFORM WAS THE SOLE CAUSE OF SMON, THAT THE STATE AND THREE DRUG MANUFACTURERS WERE LEGALLY RESPONSIBLE FOR THE DISEASE, AND THAT THE DEFENDANTS MUST PAY YEN 3,250 MILLION IN DAMAGES. TANABE SEIYAKU COMPANY, ONE OF THE THREE DRUG FIRMS INVOLVED IN CASE, APPEALED THE DECISION AND STATED ITS DETERMINATION TO CONTINUE FIGHTING TO PROVE THAT SMON IS VIRUS-CAUSED, AND TO REFUSE OFFERS OF OUT-OF-COURT SETTLEMENT TALKS.

2. ON AUG. 17, THE STATE APPEALED AGAINST THE TOKYO DISTRICT COURT DECISION. FOLLOWING THE STATE ACTION,
UNCLASSIFIED

UNCLASSIFIED

PAGE 02 TOKYO 15265 01 OF 02 240249Z

TAKEDA AND CHIBA-GEIGY QUICKLY FOLLOWED THE STATE'S LEAD IN LODGING APPEALS. MEANWHILE, SOME OF THE 133 PLAINTIFFS ALSO APPEALED, CLAIMING THAT THE COURT HAD FAILED TO HOLD THE STATE LEGALLY RESPONSIBLE FOR SMON CASES BEFORE 1967. HEALTH AND WELFARE MINISTER OZAWA EXPLAINED THAT DECISION TO SEEK HIGHER COURT'S RULING WAS TAKEN BECAUSE THE LOWER COURT'S VERDICT WOULD HAVE

SERIOUS EFFECTS NOT ONLY ON THE ADMINISTRATION OF PHARMACEUTICAL AFFAIRS BUT ALSO ON OTHER AREAS OF ADMINISTRATION.

3. THE RULING MAY HAVE CONSIDERABLE EFFECT ON OTHER SMON SUITS NOW PENDING IN TOKYO AND 23 OTHER COURTS THROUGHOUT JAPAN INVOLVING OVER 4,500 PLAINTIFFS, AS WELL AS ON SUITS CONCERNING ADVERSE EFFECTS OF CORAGIL AND CHLOROQUINE, DRUGS FOR HEART AND LIVER AILMENTS. IN THE KANAZAWA SMON CASE (REF B), STATE RESPONSIBILITY WAS DETERMINED TO EXIST FROM 1953, WHEN MHW FIRST LICENSED MANUFACTURE OF QUINOFORM. MHW APPEALED IMMEDIATELY. IN THE TOKYO CASE, THE JUDGE HELD THAT THE STATE COULD HAVE PREDICTED SIDE-EFFECTS OF QUINOFORM AFTER 1967 WHEN OFFICIAL GUIDELINES FOR CHECKING SUCH EFFECTS WERE ADOPTED AND THE STATE WAS ORDERED TO PAY ONE-THIRD OF THE DAMAGES.

4. IN THE OKAYAMA SMON CASE, AN OUT-OF-COURT SETTLEMENT WAS REACHED ON AUG. 4 BETWEEN THE STATE AND A NUMBER OF PLAINTIFFS. TANABE REFUSED TO PARTICIPATE. IN THIS SETTLEMENT, THE STATE ADMITTED THAT SMON WAS CAUSED BY DRUGS CONTAINING QUINOFORM, THAT IT WAS RESPONSIBLE FOR SOLVING VARIOUS SMON RELATED PROBLEMS AND THAT IT WOULD EXERT ITSELF TO PREVENT SUCH DRUG-CAUSED PROBLEMS IN THE FUTURE. THE STATE WOULD PAY ONE THIRD OF AWARDED UNCLASSIFIED

UNCLASSIFIED

PAGE 03 TOKYO 15265 01 OF 02 240249Z

DAMAGES, THE SAME PERCENTAGE AS WAS DETERMINED IN THE TOKYO CASE.

COMMENT: WITH TANABE HOLDING OUT AND THE STATE AND TWO OTHER DRUG FIRMS APPEALING THE TOKYO DISTRICT COURT RULING, NO END IS IN SIGHT FOR RESOLUTION OF THE MAJORITY OF SMON CASES NOW PENDING, BUT THE TOKYO RULING AND THE OKAYAMA SETTLEMENT SHOW THE MOVEMENT THAT EXISTS TOWARD WHAT MAY EVENTUALLY BE A FAIRLY STANDARDIZED FORMULA FOR SETTLEMENT. EVEN SO, THE LATEST TOKYO RULING HAS SERIOUS SOCIAL AND EVEN ECONOMIC IMPLICATIONS FOR THE FUTURE. INEVITABLY, THE GOVERNMENT (MHW) WILL BECOME INCREASINGLY CAUTIOUS AND STRICT IN LICENSING NEW DRUGS, WITH THE RESULT THAT NOT ONLY DOMESTIC BUT FOREIGN DRUG MAKERS MAY ENCOUNTER DIFFICULTY IN MARKETING THEIR PRODUCTS HERE. ALREADY, MHW IS WORKING HARD TO REVISE THE PHARMACEUTICAL AFFAIRS LAW TO ENSURE SAFETY AND EFFICACY OF DRUGS. HOWEVER, SAFE AND EFFICACIOUS DRUGS ALONE ARE NOT SUFFICIENT TO PREVENT RECURRENCE OF SMON-TYPE CASES: A MAJOR FACTOR BEHIND THE WHOLE PROBLEM IS THE OVERUSE OF DRUGS IN JAPAN AND THE CONSEQUENT OCCURRENCE OF SIDE-EFFECTS. THIS HAS BEEN COMPOUNDED BY

DEFECTS IN THE CURRENT MEDICAL INSURANCE AND MEDICAL
CARE SYSTEMS IN JAPAN WHICH RELY HEAVILY ON DRUGS IN

TREATING DISEASES. STATISTICS SHOW THAT ABOUT 40 PER CENT
OF JAPAN'S MEDICAL EXPENDITURE (YEN 7,660 BILLION FOR
FY 1976) WAS FOR DRUGS, AND ABOUT 80 PER CENT OF DRUGS
MANUFACTURED (YEN 2,100 MILLION) HAVE BEEN ADMINISTERED TO
PATIENTS BY DOCTORS. DIRECT SALE OF DRUGS BY DOCTORS

UNCLASSIFIED

NNN

UNCLASSIFIED

PAGE 01 TOKYO 15265 02 OF 02 240249Z
ACTION OES-09

INFO OCT-01 EA-12 ISO-00 HEW-06 CIAE-00 DODE-00 INR-10
NSAE-00 PA-02 ICA-20 SP-02 L-03 EB-08 COME-00
MED-05 /078 W

-----092016 240331Z /73

R 240240Z AUG 78
FM AMEMBASSY TOKYO
TO SECSTATE WASHDC 0628

UNCLAS SECTION 02 OF 02 TOKYO 15265

TO PATIENTS HAS BEEN A MAJOR SOURCE OF INCOME FOR
PHYSICIANS. MANSFIELD

UNCLASSIFIED

NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 jan 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: LITIGATION, DRUGS, COURTS, COURT DECISIONS
Control Number: n/a
Copy: SINGLE
Draft Date: 24 aug 1978
Decaption Date: 01 jan 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 jan 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1978TOKYO15265
Document Source: CORE
Document Unique ID: 00
Drafter: n/a
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D780345-1257
Format: TEL
From: TOKYO
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1978/newtext/t19780826/aaaaavkd.tel
Line Count: 152
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 2d47105c-c288-dd11-92da-001cc4696bcc
Office: ACTION OES
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 3
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: 77 TOKYO 12626, 78 TOKYO 3470
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 29 mar 2005
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: N/A
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 1628005
Secure: OPEN
Status: NATIVE
Subject: TOKYO DISTRICT COURT RULING ON SMON CASE
TAGS: TBIO, JA
To: STATE
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/2d47105c-c288-dd11-92da-001cc4696bcc
Review Markings:
Sheryl P. Walter
Declassified/Released
US Department of State
EO Systematic Review
20 Mar 2014
Markings: Sheryl P. Walter Declassified/Released US Department of State EO Systematic Review 20 Mar 2014